

Corporation, North Hollywood, Calif."; and (box) "Trim-All An Appetite Depressant * * * Each Trim-All Timed Capsule contains: * * * Lose Weight—Look Better, Feel Better * * * Windsor Corporation * * * 18489."

RESULTS OF INVESTIGATION: The article in the drum was to be repacked into the boxes labeled "*Allergy capsules*" and the article in the carton was to be repacked into the boxes labeled "Trim-All."

LIBELED: 5-17-60, S. Dist. Calif.

CHARGE: 502(a)—when shipped and while held for sale, the name of the article "*Allergy Capsules*" and the labeling which accompanied the article contained false and misleading representations that the article was an adequate and effective treatment for all allergic conditions, vasomotor rhinitis, urticaria, hay fever, and asthma; and the name of the article of "*Trim-All capsules*" and the labeling which accompanied such article contained false and misleading representations that the article was capable of causing all users to have a trim figure; and that such article was an appetite-depressant and would cause the user to lose weight; and 505(a)—both articles were new drugs within the meaning of the law and applications filed pursuant to the law were not effective with respect to such drugs.

DISPOSITION: 7-11-60. Default—destruction.

DRUGS REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

6365. Penicillin G potassium tablets. (F.D.C. No. 44053. S. No. 49-260 P.)

QUANTITY: 549 btl. at San Francisco, Calif.

SHIPPED: 11-17-59, from Hoboken, N.J., by Morse Laboratories, Inc.

LABEL IN PART: "100 Buffered Penicillin Tablets Crystalline G Potassium 200,000 Units."

RESULTS OF INVESTIGATION: The article was labeled as described above after its arrival at San Francisco, Calif.

LIBELED: 2-5-60, N. Dist. Calif.

CHARGE: 502(1)—when shipped, the article was composed wholly or in part of penicillin and was from a batch with respect to which a certificate or release had not been issued pursuant to 507, since effective exemption or supplemental certification of the batch had not been obtained.

DISPOSITION: 5-12-60. Consent—claimed by Morse Laboratories, Inc., and brought into compliance with the law.

6366. Sopamycetin chloramphenicol capsules. (F.D.C. No. 44747. S. No. 2-401 R.)

QUANTITY: 1 90-capsule btl. at Fort Lauderdale, Fla.

SHIPPED: 2-16-60, from West Palm Beach, Fla., by Medical Associates Corp., after having been imported into the United States.

LABEL IN PART: (Ctn. and btl.) "Sopamycetin Chloramphenicol Capsules * * * ets Sopar Brussels-Belgium Each capsule contains 250 mg. Chloramphenicol SUP XV Made in Belgium."

RESULTS OF INVESTIGATION: Analysis showed that the article contained the declared amount of chloramphenicol.

LIBELED: 8-3-60, S. Dist. Fla.

CHARGE: 502(f)(2)—when shipped, the labeling failed to bear the warning statement that chloramphenicol should not be used indiscriminately or for

minor infections, since certain cases of serious blood dyscrasias (aplastic anemia, thrombocytopenic purpura, granulocytopenia, and pancytopenia) have been associated with the administration of chloramphenicol, and the statement that when prolonged or intermittent administration is required, adequate blood studies should be carried out; 502(1)—the article was a drug, chloramphenicol, and was not from a batch with respect to which a certificate or release had been issued pursuant to 507, and it was not exempt from such requirements by regulations promulgated pursuant to 507; and 503(b) (4)—the article was a drug subject to the provisions of 503(b) (1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: 11-14-60. Default—destruction.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

6367. Amphetamine sulfate tablets, dextro-amphetamine tablets, and Dexobarbital tablets. (F.D.C. No. 43630. S. Nos. 74-662/7 P, 74-669/70 P.)

QUANTITY: 24 1,000-tablet unlabeled btls. of amphetamine sulfate, 15 1,000-tablet labeled btls. of dextro-amphetamine sulfate tablets, and 3 1,000-tablet btls. of Dexobarbital, in possession of Robert Rubin Yablon, t/a Sharon Rexall Drugs, Chicago, Ill.

SHIPPED: Prior to 10-28-59, from outside the State of Illinois.

LIBELED: 10-30-59, N. Dist. Ill.; amended 9-23-60.

CHARGE: 502(b) (1)—while held for sale, the articles (all lots) failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor; 502(b) (2)—the article (24 btls.) failed to bear an accurate statement of the quantity of contents in terms of weight, measure, or numerical count; 502(f) (1)—the labeling of the articles (all lots) failed to bear adequate directions for use and the articles were not exempt from such requirement since they were not to be dispensed upon prescription in accordance with Section 503(b) (1); and 502(i) (2)—the article (15 btls.) was an imitation of another drug, namely, Dexedrine Sulfate.

DISPOSITION: 11-7-60. Robert Yablon, claimant, having filed an answer denying that the articles were misbranded, and the Government having filed a motion for summary judgment on the ground that there was no genuine issue of material fact between the parties in regard to the misbranding of the articles under 502(b) (1) and (2), and the claimant having failed to make any objection to such motion, judgment of condemnation was entered and the articles were ordered destroyed.

6368. Lone Indian Herb Tonic. (F.D.C. No. 44432. S. No. 71-277 P.)

QUANTITY: Undetermined number of 8-oz. btls. at Baxter, Ky., in possession of B. Daniel Fannon, t/a Jot-Em-Down Store.

SHIPPED: The powdered aloes ingredient of the article had been shipped from Knoxville, Tenn., on an unknown date.

LABEL IN PART: "NBS Lone Indian Herb Tonic Nerve, Blood & Stomach
* * * This is a mild laxative Made from the Apple Family: Bitter Apple, Orange Apple, Aloes Powders, Salicylic, Red Cherry Powders and Distilled

*See also No. 6366.